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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/700,434	02/28/2001	Wilfried Fischer	2727-130	5919

20999 7590 02/06/2004

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EXAMINER	
GOLLAMUDI, SHARMILA S	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 02/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/700,434	FISCHER, WILFRIED	
	Examiner	Art Unit	
	Sharmila S. Gollamudi	1616	

-- The MAILING DATE of this communication appears on the c ver sheet with the c rrespondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 November 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4,5,8,10-15,17-24 and 26-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4,5,8,10-15,17-24 and 26-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Receipt of Amendment to Claims received November 14, 2003 is acknowledged.

Claims **1, 4, 5, 8,10-15,17-24 and 26-32** are pending in this application. Claims 2-3, 6-7, 9, and 16 stand cancelled.

Claim Objections

Claims 17-18 are objected to because of the following informalities: The claims are duplicate claims reciting the same limitations. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5 and10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The independent claim 1 recites consisting language wherein the transdermal system (TS) can only contain four layers: a cover layer, a protective layer, a polymer layer, and an optional adhesive layer. Further, the applicant has excluded additional ingredients in the polymer layer. However, depending claims 5 and 10 recite two adhesive layers. This is indefinite since the parent claims restricts the claim to only four layers. Further clarification is requested.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 8, 10-12, 17-20, 28, and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 95/24172.

WO 95/24172 discloses transdermal delivery system, which has a backing (cover layer), drug composite layer, and a release liner (protective layer) (Note Fig. 2-3). The reference discloses a gelled drug layer containing hydroxypropylcellulose (water-soluble polymer) with nicotine, which is further combined with an adhesive polymer (water-insoluble polymer) to form the drug composite. See pg. 19, line 1 and Fig. 1. The art reads in instantly claimed thickness 0.001-0.20 inches equals 25-508 micrometers (pg. 16, lines 20-23). The backing and release liner are made of silicon polyester (pg. 15, line 5 and Ex. 2).). WO teaches the use of the device for treating nicotine withdrawal (pg. 2, lines 5-23). WO discloses the use of the device for treating nicotine withdrawal (pg. 2, lines 5-23). WO 95/24172 discloses pressure-sensitive acrylic polymer (water-insoluble polymer) as the adhesive (pg. 16, lines 23-37 and claim 9). The method of making includes applying an adhesive layer onto the backing and release liner. The gelled drug is then applied to the adhesive layers to form the drug composite layer, which contains a water-soluble polymer (HPC), a water-insoluble polymer (the adhesive), and an active.

*Note that the phrase "adapted to be delivered in a surge upon breakdown of the polymer layer" is intended use and intended use without a structural limitation itself does not hold patentable weight. Further, since the reference utilizes only one type of

adhesive polymer for the drug composite layer, this reads on the recitation of "a non-water-soluble polymer".

Claims 1, 5, 8, 10-12, 17-20, 28, and 30-31 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 89/07959.

WO 89/07959 discloses an occlusive body patch for transdermal administration of active agents. WO discloses the method of making a patch that includes a impermeable aluminized polyester backing material (A), nicotine and methylcellulose drug reservoir incorporating a perforated membrane made of either polypropylene or polyethylene (B), an pressure-sensitive adhesive layer (35 microns thick) (C), an Akrosil 75 micron thick release liner (D). See example 1, abstract, and figures. WO discloses mixing nicotine with a water-soluble polymer (methyl cellulose) and the hydrophobic polymer is a microporous polymer such as polypropylene or polyethylene (Note Abstract, pg. 15, lines 22-25, and pg. 7, lines 11-25).

*Note that the phrase "adapted to be delivered in a surge upon breakdown of the polymer layer" is intended use and intended use without a structural limitation itself does not hold patentable weight.

Response to Arguments

Applicant argues that WO 89/07959 does not teach surge release upon breakdown.

Applicant's arguments have been fully considered but they are not persuasive. The examiner points out that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in

order to patentably distinguish the claimed invention from the prior art. In instant case, applicant claims that the transdermal device is different from the prior art because of it release; however in a product claim the structure of the product is evaluated for patentability and not how it functions upon use. The prior art is not structurally distinguishable over the prior art since claim 1 limits the polymer layer to a water-soluble polymer (WO's methyl cellulose), an active (WO's nicotine, and a water-insoluble polymer (WO's hydrophobic polymer that forms the membrane). The examiner points out that the "consisting language" does not overcome the prior art. The rate-controlling polymer is not excluded by the claims since the polymer layer clearly allows for a water-insoluble polymer and WO's hydrophobic membrane (rate-controlling polymer) used in the drug composite layer reads on this. Further, this hydrophobic membrane is part of the drug polymer composite and not a layer in itself and therefore reads on the instant invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 13-15, 21-24, 26-27, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 95/24172.

WO 95/24172 discloses transdermal delivery system, which has a backing (cover layer), drug composite layer, and a release liner (protective layer) (Note Fig. 2-3). The reference discloses a gelled drug layer containing hydroxypropylcellulose with nicotine which is further combined with an adhesive polymer to form the drug composite. (pg. 19, line 1 and Fig. 1). The art reads in instantly claimed thickness 0.001-0.20 inches equals 25-508 micrometers (pg. 16, lines 20-23). The backing and release liner are made of silicon polyester (pg. 15, line 5 and Ex. 2).). Other materials that may be used for the backing layer are polyterephthalic acid ester, polyurethane, polyethylene, or polypropylene (g. 15). WO teaches the use of the device for treating nicotine withdrawal (pg. 2, lines 5-23) and suggests other gelling agents other than HPC, such as petroleum jelly, etc (pg. 19). WO discloses the use of the device for treating nicotine withdrawal (pg. 2, lines 5-23). WO 95/24172 discloses pressure-sensitive acrylic polymer (water-insoluble polymer) as the adhesive (pg. 16, lines 23-37 and claim 9). The method of making includes applying an adhesive layer onto the backing and release liner. The gelled drug is then applied to the adhesive layers to form the drug composite layer, which contains a water-soluble polymer (HPC), a water-insoluble polymer (the adhesive), and an active. The reference teaches the use of other drugs such as hormones, vasoconstrictors, etc. that are volatile or heat sensitive. See page 10 and 14.

The reference does not exemplify all the instant materials for the cover layer and protective layer respectively. Further the reference does not exemplify the instant drug testosterone and nitroglycerine.

It is deemed obvious to one of ordinary skill in the art at the time the invention was made to look to the guidance of WO and utilize the instant materials for a given layer. One would be motivated to do so since WO teaches the suitability of several materials including the instant materials for both layers. Therefore, one would be motivated to select the material of choice with the expectation of similar results. It is deemed obvious to substitute nicotine with instant drug since WO teaches the substituting of one volatile drug for another and teaches the suitability of hormone and vasoconstrictors. Therefore, one would be motivated to utilize the instant drug depending on the condition to be treated.

Claims 13-15, 21-27, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 89/07959.

WO 89/07959 teaches an occlusive body patch for transdermal administration of active agents. The device contains a backing layer (polyester), a drug reservoir containing a perforated membrane, a pressure-sensitive adhesive, and a release liner. WO teaches mixing nicotine with a water-soluble polymer (methyl cellulose) and the hydrophobic polymer is a microporous polymer such as polypropylene or polyethylene (Note Abstract, pg. 15, lines 22-25, and pg. 7, lines 11-25). The reference teaches the optional use of tea tree oil in the polymer layer. See page 15. The perforations in the active layer allow it to come in contact to the cover layer and adhesive layer (35

micrometers). A non-woven fabric is taught to form an area-reducing mesh. See page 13. Further, the reference discloses that nitroglycerine may be substituted for nicotine and teaches the use of testosterone (pg. 11, line 11 and claim 11).

WO does not exemplify all instant materials.

It is deemed obvious to one of ordinary skill in the art at the time the invention was made to look to the guidance of WO and utilize the instant materials for a given layer. One would be motivated to do so since WO teaches the suitability of several materials including the instant materials for both layers. Therefore, one would be motivated to select the material of choice with the expectation of similar results. Further, it is deemed obvious to substitute nicotine with instant drug since WO teaches the substituting of one volatile drug for another and teaches the suitability of hormone and vasoconstrictors. Therefore, one would be motivated to utilize the instant drug depending on the condition to be treated.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO 95/24172 or WO 89/07959 in view of Wick et al (5679373).

As set forth above, WO 95/24172 and WO 89/07959 teach transdermal systems. The references teach HPC and methylcellulose as the water-soluble polymer in the drug layer.

The references do not teach the use of gelatin as the water-soluble polymer.

Wick et al teach a transdermal patch that has a backing layer, a release layer, an adhesive layer, and a drug layer (Note Figure). Wick teaches the active agent

permeable adhesive layer to be dermatologically acceptable such as methylcellulose or gelatin, among others which permits drug migration (col.16, line 59 to col. 17, line19).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute gelatin for the water-soluble to yield the instant invention. One would be motivated to do so since Wick et al teach methylcellulose and gelatin are dermatologically acceptable to the skin of the host. Further, the reference teaches the functional equivalency of gelatin and the cellulose derivatives in the transdermal device, i.e. both are water-soluble polymers used in the drug layer. Therefore, one would be motivated to use gelatin in the WO references with the expectation of similar results.

Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO 95/24172 or WO 89/07959 in view of Place et al (5242391).

As set forth above, WO 95/24172 and WO 89/07959 teach transdermal systems. The references teach the use of instant drugs.

The references do not teach the specific combination of instant drugs.

Place et al teach the treatment of erectile dysfunction. On column 3, a line 12-20, Wick discloses the use of testosterone for the treatment of impotence in the prior art. Place teaches the topical application of nitroglycerin to treat impotence (col. 4, lines 30-51).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teaching of WO 95/24172 or WO 89/07959 and Place et al use a mixture of nitroglycerin and testosterone in a transdermal system. One

would be motivated to do so with the expectation of at least as additive effect in treating impotence.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is (703) 305-2147. The examiner can normally be reached on M-F (7:30-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SSG
January 29, 2004

MICHAEL G. HARTLEY
PRIMARY EXAMINER